UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,489	05/25/2000	Ray W. Wood	029318/0596	7761

31049 7590 04/19/2006

ELAN DRUG DELIVERY, INC.
C/O FOLEY & LARDNER LLP
3000 K STREET, N.W.
SUITE 500
WASHINGTON, DC 20007-5109

EXAMINER	
QAZI, SABIHA NAIM	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/577,489	WOOD ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-40,42-45 and 47-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-40,42-45 and 47-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Non-Final Office Action

Acknowledgement is made of the response filed on. Claims 28-40, 42-45 and 47-59 are pending. No claim is allowed.

- Arguments were fully considered but are not found persuasive therefore rejections are maintained for the same reasons as set forth in our previous office action. New IDS contain references, which further confirm that at the time of invention inhalation aerosol, and use of it as presently claimed would have been obvious to one who is familiar with the art.
- Double Patenting rejection 28-40, 42-45 and 47-59 over claims 20-24 of SAIDI et al (U.S. Patent No. 6,241,969) is withdrawn because arguments are found persuasive.
- The 35 USC § 103(a) rejections over US 5747001 (WIEDMANN et al), US 6264922 (WOOD et al.), and US 5145684 (LIVERSIDGE et al.) is withdrawn as a terminal disclaimer has been filed.
- Applicant's response is silent over claim 44. How the method of administering is applied to treat diseases differently as in claim 44.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 28-40, 42-45, and 47-59 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply.

3. "Method of delivering" as claimed was not found in the specification.

4. Applicant is requested to show where is the support for "method of delivering" in the disclosure.

Rejection under 35 USC § 103(a) 1st Rejection

Claims 28-40, 42-45, and 47-59 are rejected under 35 USC § 103(a) as being unpatentable over LIVERSIDGE et al (US Patent No. 5,145,684) and FOLKE MOREN Aerosols in Medicine, Principles, Diagnosis and Therapy, (1993) Elsevier Science Publisher, Chapter 13, pages 321-350. Both references teach a method and use of drug by inhalation aerosols for drug delivery into airways that embraces Applicant's claimed invention. See the entire document.

LIVERSIDGE et al. teaches that commercial air jet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50 microns). The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective particle size of less than 400 nm. See the entire document, especially lines 47-50 in col. 1, claims, and examples.

Instant claims differ from LIVERSIDGE et al in that the instant invention has a broader scope. LIVERSIDGE does not teach aerosols.

MOREN teaches the use of inhalation aerosols for drug delivery into airways, mainly to provide a local effect in the upper or lower respiratory tract. It also teaches that drugs are widely used for local effect in the lower respiratory tract. Bronchodilators, corticosteroids, anticholinergics and antiallergic drugs are administered by means of oral inhalation. The advantages being decreased systemic side effects, and in some cases rapid onset of action See 2nd paragraph on page 321. See also 1st and 2nd paragraphs on page 322, see nasal inhalation on page 337, particle size on page 338, see section 4.1 and 4.1.1 where aqueous aerosols are taught.

It would have been obvious to one skilled in the art at the time of invention was made to prepare the method of delivering an aerosol to lungs as claimed by the combined teachings of the two references cited above for the treatment of respiratory diseases by using aerosols because LIVERSIDGE et al teaches the average particle size, surface modifier, and all other limitations of the presently claimed invention and MOREN teaches aerosols and delivery to respiratory tract using poorly soluble drugs such as steroids.

Referring to claim 44 Applicants have not shown how the method of treating various diseases is different from the prior art teaching by using their delivery method.

In absence of any criticality and/or unexpected results instant invention is considered *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Rejection under 35 USC § 103(a) 2nd Rejection

Claims 28-40, 42-45, and 47-59 are rejected under 35 USC § 103(a) as being unpatentable over LIVERSIDGE et al (US Patent No. 5,145,684), A.R. GENNARO Remington's Pharmaceutical Sciences, 17th Edition, (1985), Chapter 93, pages 1670-1677 and DIETER KOHLER, Aerosols in Medicine, Principles, Diagnosis and Therapy, Edited by F. Moran, Chapter 12, (1993), pages 303 319. All the references teach a method that embraces Applicant's claimed invention.

LIVERSIDGE et al. teaches that commercial air jet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50 microns). The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective particle size of less than 400 nm. See the entire document, especially lines 47-50 in col. 1, claims, and examples.

Instant claims differ from LIVERSIDGE et al in that the instant invention has a broader scope and use aerosols. LIVERSIDGE does not teach aerosols. GENNARO and KOHLER reference teaches use of aerosol for poorly soluble drugs, absorbence, particle size and various others related to aerosols.

GENNARO reference teaches pharmaceutical aerosols in the form of solutions, suspensions, emulsions, powders and semisolids, see the entire document (see especially Table V in the left column of page 1672). The reference also teaches the preparation of aerosols for antibiotics, steroids and other difficultly soluble compounds (see last two paragraphs on page 1672 in the right column. See particle size and drug delivery into respiratory airways on pages

1674 and 1675, Table IX on page 1676 where steroids and other poorly soluble drugs are listed as medicinal agents having high potential for use as aerosol inhalation products.

KOHLER teaches the advantages of drug administration via aerosols for systemic treatment over oral routes of the compounds that are poorly soluble. See the entire document especially 2nd para on page 305, TABLE 1, section 3.1 on page 309-311, TABLE 2 and section 3.3 on page 313 and last paragraph on page 315.

It would have been obvious to one skilled in the art at the time of invention was made to prepare the method of delivering an aerosol to lungs as claimed for the treatment of respiratory diseases by the combined teachings of the above cited references, because LIVERSIDGE et al teaches the average particle size, surface modifier, and all other limitations of the presently claimed invention and GENNARO and KOHLER references teach the use of aerosols for poorly soluble drugs and inhalation products and treatment of asthma and other respiratory illness.

At the time of invention the use of aerosols was known in the art. All the claimed invention is taught by LIVERSIDGE except aerosols. It would have been *prima facie* obvious to use aerosols because prior art teaches the use for the same purpose.

Referring to claim 44 Applicants have not shown how the method of treating various diseases is different from the prior art teaching.

In absence of any criticality and/or unexpected results instant invention is considered *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SABIHA QAZI, PH.D
PRIMARY EXAMINER